201-14640

PEOPLE FOR THE ETHICAL TREATMENT OF ANIMALS

HEADQUARTERS
501 FRONT STREET
NORFOLK, VA 23510
TEL 757-622-PETA
FAX 757-622-0457

August 1, 2003

RECEIVED
OPPT CBIC

2003 AUG 4 AM 11:12

Marianne L. Horinko
Acting Administrator
U.S. Environmental Protection Agency
Ariel Rios Building (1101A)
1200 Pennsylvania Ave. NW
Washington, DC 20460

Re: Comments on the API's Test Plan for the Lubricating Oil Basestocks Category

Dear Ms. Horinko:

The following comments on the American Petroleum Institute's (API) high production volume (HPV) chemical test plan for the lubricating oil basestocks category are submitted on behalf of People for the Ethical Treatment of Animals, the Physicians Committee for Responsible Medicine, the Humane Society of the United States, the Doris Day Animal League, and Earth Island Institute. These health, animal protection, and environmental organizations have a combined membership of more than ten million Americans.

The API's test plan for lubricating oils basestocks includes 39 different substances grouped into three general subcategories of unrefined and mildly refined, highly and severely refined, and residual base oils. All substances in the category are actually complex mixtures of hydrocarbon compounds, with the toxicity of many of these compounds being well characterized, either as individual compounds or as part of other complex mixtures. We support the formation of a scientifically defensible category with a number of substances, as this results in fewer animals being used in the SIDS battery. However, we remain very concerned about the remaining proposed testing on animals, namely two dermally administered repeat dose/reproduction/ developmental studies per OECD test guideline 422.

As with many of the API's previous HPV test plans, the current testing proposals are unnecessary. If this test plan is conducted in its present form, approximately 1,350 animals will be killed. Our objections are summarized as follows:

1. The API plan is lacking compositional data on oils, specifically the spectrum of polynuclear aromatic hydrocarbons (PACs, also abbreviated as PNAs or PAHs) content. Since PACs are the primary identified toxic compound in this HPV test category, and PAC toxicity is well characterized (see below), adequate data already exist to characterize the toxicological hazard of these compounds, *if* the API were to properly characterize their analytical chemistry.

2. The category should be expanded to cover a broader range of heavy-end hydrocarbon substances and combined with the waxes and related compounds category.

3. The test plan does not include or refer to existing data on TPH (ATSDR 1995), Fuel Oils (ATSDR 1995) or Mineral oils (ATSDR 1997), nor does it include any analysis of human exposure to these compounds.

The fundamental physical/chemical properties of these compounds include high molecular weights, low water solubility, and occurrence as a viscous liquate phase. As described in the test plan, the toxicity of these compounds is derived from the "undesirable" compounds found in the less refined substances in this category. It is unlikely that the approach proposed in this test plan will produce meaningful data, since tests are being proposed even though it is these composition differences that determine toxicity, and a complete discussion of the composition of different category members is lacking in the API's test plan analysis.

Before deciding to conduct additional animal testing, the more scientific approach would be to first develop more data on the composition of the proposed test material. Once the composition has been better characterized, the complex mixtures' toxicology can then be evaluated based on the toxicities of the constituent chemicals. For example, abundant information already exists on the toxicology of PACs and many other petroleum fractions,[2] as well as on their many hazards. Therefore, with the combination of expanded composition information and existing toxicological information on the toxic components, an enlightened basis is provided for evaluating toxicity of these compounds. We therefore recommend further chemical characterization and extrapolation of known toxicities on the components (which requires *no* animal testing) in lieu of the API's default to animal testing of a chemical mixture which has had inadequate chemical characterization from work in the analytical laboratory.

It is unclear why the API persists in its pattern of subjecting animals to suffering in unneeded toxicity studies rather than conducting more work at the non-animal chemistry level which, along with the use of the extensive toxicity data available on PACs, would meet the demands of the HPV program. We hope that the EPA, with its stated desire to reduce the use of animals in this program, will agree with this approach and insist that the API reconsider its proposal. When a choice is available between using animals in toxicity tests versus doing more work in the chemistry lab, the EPA should encourage the API to do its chemistry homework and to spare the animals.

The API is proposing additional repeat dose/reproductive/developmental studies despite the fact that long-term studies have been conducted to evaluate these very same endpoints in heavy vacuum gas oil, which is similar to the mildly and unrefined oils. This study showed only minor effects at high doses (1000 mg/kg/day, which is normally considered to be a "limit dose"). In addition, studies of a highly refined mineral oil showed no reproductive or developmental effects at the extremely high doses of 5 ml/kg/day.[3]

As stated in the API's test plan, the primary toxicological effect is a result of undesirable compounds in the less refined and residual oils. The extensive database on repeat dose testing of animals using white oils is also indicative of the toxicity arising from less refining. If the API were to present more in-depth chemical data on these oils, and apply the existing reproduction/ developmental data from vacuum gas oil and the repeat dose studies from the range of oils, it is quite clear that the hazards associated with these oils could be assessed. In addition, further

information can be gained from toxicological studies of automotive engine oils, mineral oil-based hydraulic fluids, and well characterized hydrocarbon mixtures containing many of the same compounds such as diesel, kerosene, and Stoddard solvent.

The problems associated with this test plan also dramatically affect the updated test plan presented by the API on Waxes and Related Substances, as the primary toxicological concerns in this category arise from oil components in impure waxes. **In addition to revising this test plan, we implore API to revisit its Waxes test plan (which we commented on in December 2002), removing animal testing and further incorporating the data available in this test plan. As we previously commented, it would be appropriate to combine these two test plans into a single, larger category to assess the hazards of these generally non-toxic substances.**

Unfortunately, the API's proposal for testing the lubricating oil basestocks category suffers from the same set of problems that has characterized previous API test plans, dating as far back as its proposal to test petroleum coke. The lack of thoughtful analysis and the failure to combine testing with similar compounds, has led to a gross and unnecessary use of animals in laboratory testing. We urge both the API and the EPA to seriously consider these comments and concerns and to revise the testing proposal accordingly.

I can be reached at 757-622-7382, ext.1304, or via e-mail at JessicaS@peta.org, should you wish to discuss these issues further.

Sincerely,

Jessica Sandler, MHS
Federal Agency Liaison

[1] ATSDR. (1995). Toxicological Profile For Polycyclic Aromatic Hydrocarbons (PAHs). Prepared By Research Triangle Institute for the U.S. Department Of Health And Human Services. Public Health Service.

[2] ATSDR. (1999). Toxicological Profile For Total Petroleum Hydrocarbons (TPH). Prepared by Research Triangle Institute for the U.S. Department Of Health And Human Services/Public Health Service.

[3] McKee, R.H. *et al.* (1987a). Assessment of the potential reproductive and subchronic toxicity of EDS coal liquids in Sprague-Dawley rats. *Toxicol* 46, 267-280.

[4] McKee, R.H. *et al.* (1987b). Developmental toxicity of EDS recycle solvent and fuel oil. Toxicol 46, 205-215

[5] IPCS/WHO. (1982). Environmental Health criteria 20: Selected petroleum products. Geneva: WHO.